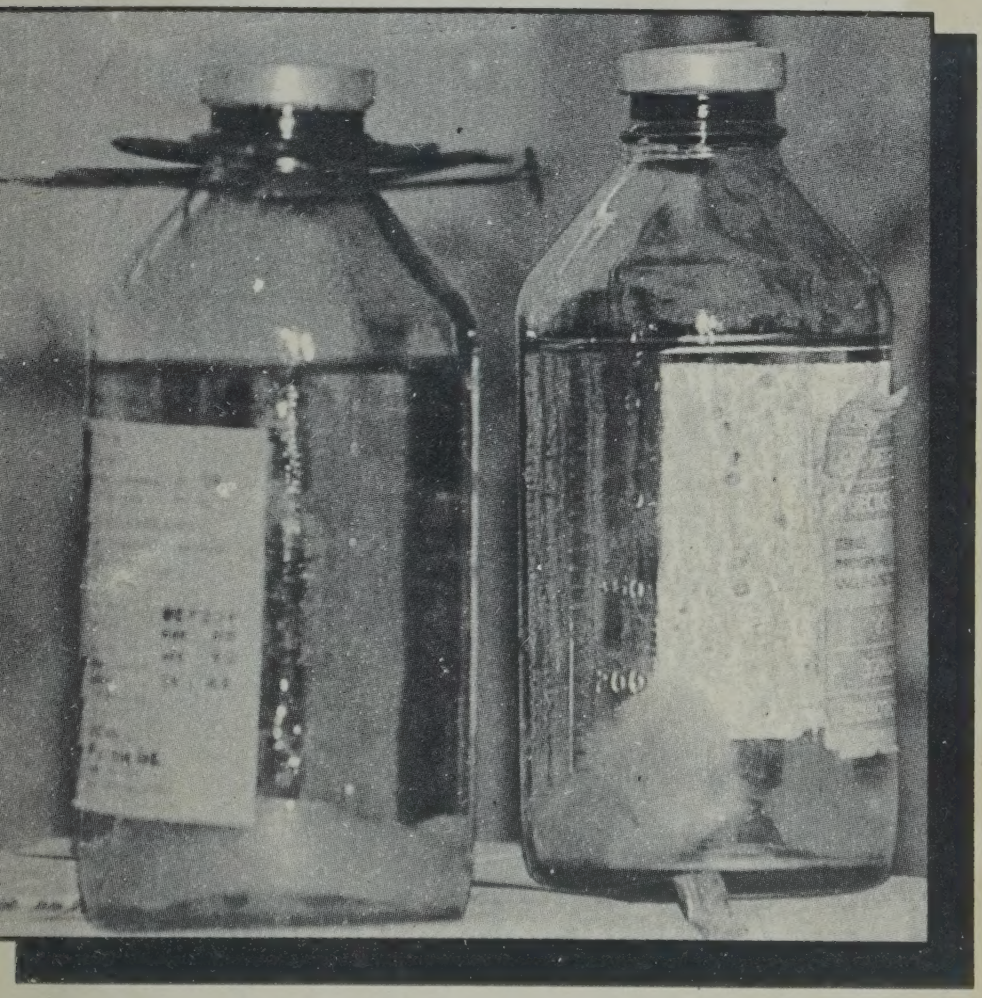
THE KILLER FLUIDS

(A Report on the I.V. Fluids Contamination Case)



Voluntary Health Association of India

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Foreword

Public memory is usually short. It is even shorter in our country where human tragedies affect the lives of so many citizens so very often. It is therefore natural that the IV Fluid contamination tragedy will soon be a matter of the past until another similar incident hits the headlines again.

We in VHAI are greatly concerned by the frequency of such public health tragedies and the success with which public hue and cry are successfully silenced by appointing commissions and investigations. Therefore, for the last couple of years, we are ourselves investigating such incidents to keep the policy makers, administrators, health professionals and the public informed of the real facts. Other facts that emerge from these investigations are the callousness and total disregard for human life among a certain sector of society and the utter ineffectiveness of the health system in tackling such serious events.

We hope, through these reports, we will effectively build up solidarity with other like-minded organisations and individuals so that we stand together to struggle effectively against the degeneration of our public health system.

-- Alok Mukhopadhyay
Executive Director, VHAI

Introduction

The Lentin Commission investigated the deaths of 14 patients who were admitted to the JJ Hospital, Bombay in 1986 and administered adulterated glycerol. The Commission's report shook up both the public and the medical world.

The report brought out the brutal truth about the cause of the tragedy and how such tragedies were bound to recur if urgent measures were not taken to prevent their recurrence. Had it not been for the tenacious interest of, and follow up by, socially conscious journalists, the public would have never known of the tragedy in the first place, nor of its follow up through accounts of the proceedings of the hearings which were also reported in the press.

The Lentin Commission report must be read by all those concerned about people and their health, those who wish to understand the anatomy of such tragedies, understand the close nexus that exists between the 'producers' of such products and the 'permission givers.'

The I.V. contamination deaths in Delhi must be seen in this context. This summary report reflects the tip of an iceberg. At a time when the Drug Policy is being reviewed, it is essential that certain stringent measures be taken to ensure that such tragedies do not recur.

The much awaited drug policy of 1986 unfortunately systematically glossed over the legitimate demands by the consumer and health groups for a Rational Drug Policy. Instead of which, what the nation was presented with was merely an increase in drug prices under the policy document called "The Rationalisation Measures for Quality Control and Growth of the Pharmaceutical Industry" prepared by the Chemicals Ministry under the Industry Ministry.

The key issues of ensuring production, distribution and availability of quality essential life-saving drugs at reasonable prices -- starting with formulation of a graded essential drug list based on the health needs of our people, identification and withdrawal of hazardous, irrational and non-essential drugs in a phased manner, starting with drugs recommended for banning by the government's own committees were totally marginalised. Availability of unbiased drug information to the medical professionals and the consumers must be ensured. Drugs with common serious side effects must carry consumer caution and warnings in regional languages, and advertisement of over-the-counter drugs in the media must be allowed only if the contents i.e. ingredients and their dosage and caution, are clearly indicated.

Over 2000 crores worth of over 60,000 branded formulations are being sold every year, produced by 20,000 formulators. If Good Manufacturing Practices (GMP) and stringent quality control cannot be ensured then, rather than contributing positively to the curative aspect of health care, medicines can prove to be health hazards.

Similarly, hazardous or irrational drugs whose 'quality' is assured are not in the interest of the public. Such drugs must be withdrawn, so as not to overload the already inadequate drug control machinery and ensure low cost and good quality of essential and life saving drugs.

The question is no longer just of economic wastage. In a country with around 50 per cent of the population below the poverty line it is a matter of serious concern and exploitation in the name of medicine. the issue of medicines is a rapidly emerging public health problem. In the absence of monitoring of adverse drug reaction i.e. side effects of medicines, majority

of the cases of iatrogenesis i.e. drug and doctor induced health problems, continue to be missed. It is only tragedies such as the glycerol deaths and deaths due to contaminated I.V. fluids that focus public attention on the problems related to unsafe medicines.

The Consumer Protection Act of 1986 is a tool in the hands of the consumers to take action to safeguard their interest. It is however clear that in the absence of a comprehensive public/ people oriented Rational Drug Policy, the public will continue to pay through its nose for medicines that it doesn't need and for medicines that are needed but are of questionable quality and outrageously priced. If tragedies such as that of glycerol in Bombay and contaminated I.V. fluid deaths in Delhi can result in serious introspection and policy changes, so that people are protected in the future and the guilty are brought to book, then those who died would not have died in vain.

We dedicate this short report to the memory of those who died needlessly and whose names figures in death registers of hospitals where they died and to those who died undiagnosed, unattended to, because of such adulterated, contaminated medicines in their own homes. Such tragedies should never recur -- that is the objective of this brief report.

Dr. Mira Shiva MD
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KILLER FLUIDS

"No death has been reported by the Central Government Hospitals in Delhi during the year 1988-89 due to contamination of glucose. Health being a state subject, information in respect of states are (*sic*) not available ... none of the batches (of I.V. fluids) has been reported to be found contaminated from the wards/departments of any central hospital in Delhi during 1988-89."

– Smt. Saroj Khaparde, then Minister for Health and Family Welfare, answering a question in the Lok Sabha on March 29, 1989, a month after the first press reports of I.V. fluids deaths in Delhi hospitals appeared.

Reassuring words. But words nevertheless. Can they console the families of the known and unknown many who died – *killed,* ironically, by *life saving* intravenous fluids?

It was in February 1989 that life saving I.V. fluids reportedly claimed seven lives, right in the country's capital, in prestigious government hospitals. The very same month, on February 3, a Delhi drug stockist complained to the drug control department that he had in his godown no less than 30,000 bottles of lethally contaminated I.V. fluids – 30,000 bottles, which if used, could have resulted in a virtual holocaust. This revelation should have instantly activated even the most lethargic of bureaucratic outfits. But not the Union Health Ministry. Anxious questions raised in Parliament – no less than five – begat casual replies that nothing was wrong. In March, and then again in April, alarmed Parliamentarians physically produced in Parliament bottles of

I.V. fluids with deadly fungus floating in them. "Give me your complaints in writing, I will look into them," said the Speaker.

That same month, two patients reportedly died in Safdarjung Hospital, a stone's throw away from Parliament, after being injected with contaminated I.V. fluids. The hospital authorities never officially confirmed the deaths as due to I.V. fluid contamination. Instead, they discreetly withdrew the batches of the fluid — Ringer lactate — and then issued a denial of any I.V. fluid related deaths in the hospital. No postmortems were done on the dead patients, despite the hospital's junior doctors themselves not being convinced by the official version of these deaths. And Safdarjung Hospital, despite its size and status, does not have a death review committee to probe such deaths.

The next month, in May, a doctor in the prestigious All India Institute of Medical Sciences (AIIMS) spotted a highly contaminated bottle of life saving I.V. fluid seconds before it was to be injected into a patient. When another bottle manufactured by the same company — Tablets India Ltd. — was found teeming with contaminants three months later in similar circumstances, the alarmed Resident Doctors' Association (RDA) of the hospital demanded that this company be blacklisted. The Association warned that doctors would boycott the company and ask the patients to bring I.V. fluids for their own use from outside, for their own sake.

Meanwhile, just across the road from the AIIMS, at Safdarjung Hospital, the killer fluids continued to take their toll. Shanti, a 50 year old woman, died on September 3, within half an hour of being administered a bottle of Ringer lactate.

Mohammed Izhar, a 22 year old patient, died the same morning, immediately after being given a bottle of dextrose. Nothing but the I.V. fluids they were given could have taken their lives, said the hospital's doctors, because they were not given any other drug.

That fortnight, five other patients admitted to the hospital for minor routine operations developed serious complications following administration of I.V. fluids. All five of them, and the two who died, betrayed identical symptoms: violent shivering, swelling of the face and hypoxic convulsions. The hospital's junior doctors told the press that I.V. fluid contamination was becoming so acute that every second patient injected with I.V. fluids was developing violent shivering — the first and most obvious sign of fluid contamination.

During the next fortnight, another eight patients, one after the other, hung between life and death after being injected with the fluids. One of them was Bimla Kapoor, a nurse working in the same hospital and admitted for a cystoscopy, who was given 5% dextrose manufactured by Dhavsons Pharmaceuticals. The other seven also had been given the same company's fluids.

Finally, on September 16 and 19, the hospital issued circulars to its doctors to halt using two particular batches of 5% dextrose made by Dhavsons Pharmaceuticals. Another circular on September 21 advised the doctors against using another type of I.V. fluid — normal saline — of a particular batch also produced by the same firm. And the following day, a sudden announcement over the hospital's public address system warned the doctors in the wards against using yet

another batch of dextrose from this company: an extraordinary method, following serious complications to a woman in the hospital's labour room, after she was given the fluid. *But even at this stage, there was no confirmation of widespread I.V. fluid contamination from the hospital authorities, and the Faridabad-based company continued their supply of I.V. fluids.*

Later, the hospital officially "took notice" of just four cases of adverse reactions and froze its stocks of 5% dextrose manufactured by this company, while continuing to use its normal saline fluid! The RDA's demand to blacklist this company thus continued to be ignored.

The very next week, the urgency of the RDA's demand became obvious. The doctors in the hospital's operation theatre made a shocking discovery — a *sealed* bottle of normal saline on the theatre's shelf was found not merely contaminated as in earlier cases, it also contained what appeared to be a squashed worm. This bottle, which had already expired, could have killed the patient instantaneously.

Meanwhile, obviously irked by the continuing press reports, Mr. G.P. Saxena, the Drug Controller of Delhi wrote to the Medical Superintendent of the Safdarjang Hospital: "*Fungus growth in a few bottles out of a batch of I.V. fluids is not uncommon. But such reports when they appear in the press, create baseless fears in the minds of the people.*" Taking the obvious hint, the hospital authorities started shying away from the press, and as if in warning to those junior doctors who had been exposing cases of contamination, chargesheeted two doctors for appearing in a Doordarshan newscast about the issue.

The hospital had earlier in August ordered an enquiry by its deputy medical superintendent, Dr. C.P. Bahl after two patients had died due to contaminated Ringer lactate. The report was that the two died due to "other reasons".

The RDA alleged foul play and intentional cover-up by the hospital authorities. But the latter stuck to their decision of exonerating Prem Pharmaceuticals, the Indore-based company which manufactured the Ringer lactate.

Ironically, soon afterwards, a notice came up in the hospital's ward B, asking doctors not to use the Ringer lactate manufactured by the same Prem Pharmaceuticals, as also 5% dextrose from Dhavson's Pharmaceuticals, Faridabad. The official who issued the notice had, however conveniently forgotten to sign it. This was followed by press exposes of tampering with, or destruction of, casesheets of the victims of contaminated I.V. fluids.

While the controversy thrived in the capital, reports from other parts of the country about I.V. fluid contamination saturated the print media. The bottles of death made their appearance, among other places, in the National Medical College in Calcutta, Hamidia Hospital in Bhopal and the Medical College of Jaipur. In Bhopal, the issue took on a new dimension: while in most other places the widely suspected reason for contamination had been the substandard manufacturing practices of the small companies which supply these fluids, the I.V. fluid bottles with black specks and other contaminants which appeared in Bhopal's Hamidia Hospital were manufactured by Hindustan Antibiotics Limited, a public sector company which supposedly uses the CORE

technology that is considered to be of the highest standard in the field. In welcome contrast to the manner in which the issue was handled in Delhi, however, the state government ordered freezing of the entire stock of HAL fluids and initiated an enquiry following reports of a death and another case of complications due to the fluids.

Perhaps the most serious result of the conscious cover-up bid on the part of the hospital authorities, wherever such deaths occur, is that the other hospitals cannot be alerted in time to check the recurrence of the tragedy there.

What are I.V. fluids?

I.V. fluids play a very vital part in day to day treatment of patients, in all hospitals and nursing homes. Whenever normal oral intake of food or medication becomes difficult, as in the case of accidents, serious infections, ailments causing dehydration and in many other instances, I.V. fluids serve as the only way to rehydrate and provide life saving nutrition, as well as to introduce different drugs for treatment into the patient's body.

Since I.V. fluids are injected directly into the patient's bloodstream through the veins, it is eminently important that the fluids have the highest purity and quality. Even the slightest contamination in the fluids can result in serious consequential complications, and in many cases, death itself, because the suspended particles or other forms of contamination can block the neurological, renal and cardiac systems.

Contamination – who is responsible?

From production to actual administration, I.V. fluids pass through several possible check points – the manufacturers, the stockists, the pharmacists, the doctors and the nurses. Keeping a check on the quality of I.V. fluid, compared to other drugs, is much easier. Fungus, and other suspended contaminants, are easily spotted even by the naked eye. The manufacturers of contaminated I.V. fluids on such a large scale (as evidenced, for instance, by the 30,000 bottles lying in the godown of a Delhi stockist) can never claim to be absolved of their crime merely because they had printed the statutory warning "Not to be used if the solution is not clear" on the bottle labels. If printing those words would exonerate them, however deadly their products turn out to be, that would certainly set a precedent of moral and legal perversion in the country.

The stockists of contaminated fluids have also to be held equally responsible. The Indian pharmacopea clearly mentions that dextrose for intravenous administration should be stored in a cool place. (The Martindale's Extra Pharmacopea is more explicit – it stipulates that I.V. fluid should be stored in temperatures between 2 to 25 degrees C.) How many drug stockists in India ensure this?

The Drug Control departments have been generally ignoring this storage stipulation and certifying any seedy godown as fit for I.V. fluid storage without a thought as to what would happen to the stocks, particularly during summer.

Besides, I.V. fluids being a large volume merchandise, often sold in hundreds of bottles, the stockists hardly take the

trouble to look for contaminants in individual bottles before they are consigned to the hospitals. The onus of ensuring safety is thus passed on once more, this time to the hospitals which, ultimately, are the users of these products.

Here too, the I.V. fluids pass through personnel at different levels — the pharmacists who store them, the doctors who oversee their actual infusion, and the nurses who ultimately administer these fluids to the patient. Any one of them, had they cared enough, could have taken a close look at the bottles to spot the suspended particles, which could have saved many an innocent life. Besides, when a patient is being administered a fluid intravenously, the non-sterile atmospheric air constantly keeps bubbling through into the solution. Six or more hours of continuous administration of the solution could possibly contaminate the solution, Yet, most hospitals have ignored this crucial point and, surprisingly enough, partially used bottles of I.V. fluids are commonly used the next day or even later.

One great hurdle in prosecuting those responsible for the I.V. fluid deaths, as a deterrent for others, is that it is very difficult to establish a clearcut case of I.V. fluid death that could stand in a court of law. It is not easy to tie up a death with I.V. fluids unless the adverse drug reaction was very closely monitored after the injections were administered. In the case of these fluids, unlike that of other drugs — penicillin for instance — the reactions need not always be obvious. Besides, the blame could also be shifted to other drugs that the patient would have been given along with the I.V. fluids. One of the favourite methods of covering up the incident is by labelling it as "death due to cardio-respiratory failure".

Economics or Health?

One of the strongest recommendations made by the eleventh Conference of the Indian Pharmacy Graduate Association (IPGA) on February 11, 1989 at Delhi was that *every district hospital in the country should have a plant to make I.V. fluids for its own use.*

The significance of this recommendation, as far as the health of our people is concerned, cannot be overstated in the present circumstances. One of the biggest causes of contamination in I.V. fluids is that the bottles are highly prone to developing micro-cracks during transportation. Once the hospitals start manufacturing their own I.V. fluids, this problem would naturally be averted. Besides, this would also help the hospitals themselves to ensure quality without having to depend on some obscure pharmaceutical firm in some far off corner of the country.

Yet, only a nominal number of district hospitals have their own intravenous fluid making facilities in the country today.

A case in point is the All India Institute of Medical Sciences, New Delhi which consumes about 3000 bottles of I.V. fluids per day, depending solely on small private manufacturers for its entire requirements, although it has an excellent plant capable of manufacturing a good part of its daily I.V. fluid needs. This plant presently manufactures only distilled water, and a small amount of specialised fluids like mannittol.

The Resident Doctors' Association of the hospital had tried its best to raise the issue and force the hospital authorities to

resume I.V. fluid production in the plant, in view of the widespread incidence of contamination in fluids supplied to the hospital.

Besides, in spite of numerous complaints from the wards about the quality of I.V. fluids, no attempts have been made by the hospital authorities to blacklist the firms which have been supplying these fluids. Nor has there been any effective attempt to make sure that these firms have the requisite facilities to supply I.V. fluids without inherent defects.

The explanation given out by the hospital authorities for non-production of I.V. fluids is that they lack an autoclave (a machine used for sterilisation) and a technician to run it. Both these fail to adequately convince, because the cost of an autoclave would work out to be a mere fraction of the huge annual budget of the AIIMS, and a technician cannot be impossible to find.

Interestingly, while medical experts swear that producing intravenous fluids in the hospital would mean a cut of at least 25% in the cut compared to what is being paid to private suppliers, and that the gain accruing out of this difference would itself pay for the new autoclave in a few years, the AIIMS authorities disagree. They maintain that since the overhead costs involved in producing I.V. fluids would work out to be higher, it is cheaper for them to buy these fluids from the market in spite of the hazards involved. When even the prestigious AIIMS has reduced the problem to one of simple economics while the lives of its patients are at stake, why blame our district hospitals?

What needs to be done?

As the issue of I.V. fluid deaths snowballed to crisis proportions, the Drug Controller of India, threw up this hands in despair and publicly admitted that he was in *NO* position to guarantee safe drugs because the machinery that the Government had placed at his command was inherently incapable of doing so.

A circular issued by Dr. Prem Kumar Gupta, Drug Controller of India, to his colleagues on April 22, 1989 says: "The Drugs Control Organisation at the Central and State levels... is woefully inadequate to monitor the quality and regulate the production of safe drugs..."

The same circular admits a serious lacuna in the country's drug control laws. "The act (Drugs and Cosmetics Act -1940) empowers the government to prohibit manufacturers' sale and distribution of a drug in public interest... *(But) there is no provision under which a manufacturer can be directed to withdraw a drug from the market within a specific period...*" In simple terms, even if a drug proves to be contaminated or spurious, and even if it is known to be lethal, it can remain in the market for several long years before the Government is finally able to take it off the shelves.

At this juncture, it would be worthwhile to examine the infrastructural drug quality control facilities that the country has at its disposal:

- ***Laboratories***

No drug control machinery can operate effectively unless

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it is provided with its most basic need — a laboratory and an adequate staff to decide if the seized samples are dangerous or not. The central council of health had passed a resolution that each state and union territory should have its own testing laboratory.

In this regard, on April 5, 1989, Ms. Saroj Khaparde, then Minister of State for Health and Family Welfare had made the following self-explanatory statement in Parliament: "Only the states of Maharashtra, Gujarat, Karnataka and Tamil Nadu have facilities for testing all categories fo drugs, while the states of Andhra Pradesh, Bihar, Madhya Pradesh, Orissa, Punjab, Uttar Pradesh, West Bengal, Rajasthan, Haryana and Kerala have facilities for testing only non-biological products. The remaining states and union territories do not have ANY testing facilities..."

- ***Staff***

The hands and eyes of any Drug Control department are Drug Inspectors, who are responsible for the ultimate execution of its intended actions. This is the All India situation:

No. of Drug Mfg. Units (as on date)	No. of drug sales units (as on date)	Total required numbers of drug inspectors	Existing number of drug inspectors
20,000 units	200,000 units	2,689	664

In other words, *the country has less than one fourth of the number of drug inspectors actually required. Here is a reflection of the situation in a few random instances:*

(AS ON April 1, 1989)

State/UT	Required number of Drug Inspectors	Existing number of Drug Inspectors
Maharashtra	477	81
Rajasthan	145	29
Delhi	55	19
Karnatak	105	86
Gujarat	317	85

Not a single state in India has the required number of drug inspectors. And in places like Arunachal Pradesh and the Andaman and Nicobar Islands, there is not even a single drug inspector around. (The only exception, and a very paradoxical one, is Orissa, which, for some inexplicable reason, has no less than 17 drug inspectors, whereas a mere eight would have actually sufficed).

The gravity of the situation is obvious. No state in India can claim to be sufficiently geared up to tackle the menace of dangerous drug preparations, with regard to the most basic infrastructural facilities, not to mention the following equally important aspects:

- The regular, overworked personnel of the state drug control departments cannot be expected to make much headway in tasks like unearthing spurious drug rackets and efficiently pursuing matters on a legal level. There is an urgent need to constitute specially trained cells and to set up intelligence-cum-legal cells in each state drug control body for the purpose, which has not been done so far.

- Taking into account the dire need to ensure that the manufacturers follow Good Manufacturing Practices, the regular inspecting personnel cannot be entrusted with the burden of indepth inspection of new and existing manufacturing units for this purpose. Only specially set up cells can handle this as well as screening formulations thoroughly before granting licences.

- Constant interaction with the powerful multicrore drug industry could easily have a corrupting influence on the personnel involved in drug control activity. There has to be new thought in this direction to arrest the escalation of corruption. There needs to be a special anti-corruption cell attached to each state drug control unit.

The Voluntary Health Association of India recommends the following, in addition, to strengthen our drug control system for ensuring safe drugs to the people:

1) National Drug Authority

Setting up of the National Drug Authority as recommended by the Hathi Committee, is already long overdue. It must be set up immediately with the Health Ministry as the Nodal Ministry.

2) Good Manufacturing Practices – Licensing

To ensure effective control, and recognising that the recall mechanism for substandard drugs is very poor once they are in the market, efforts have to be made to *deny* and withdraw

licenses to pharmaceutical units not following Good Manufacturing Practices.

3) *Rationality of Drugs in the Market*

The number of *formulations in the market must be restricted* to allow only *Rational* drugs so as not to overload the already inadequate drug control mechanism.

4) *Centre-State Relationship & Financing of Drug Control*

The Centre-State relationship vis-a-vis drug control needs to be very clearly defined. Central assistance for drug control, in those states where needed, ought to be facilitated.

5) *Budget Allocation*

Budget allocation for drug control has to be increased. Amounts to be obtained under the Drug Price Equalization Account for drug "over pricing" by manufacturers *must* be obtained.

6) *Drug Control Mechanism*

The Central Drug Controller's office must be strengthened, adequately staffed and be well equipped for the DCI to function effectively.

Central Drug Authorities must have collated information regarding the number of drug formulations and their

manufacturers in the country; the periodic list of licenses issued must be made available to the DCI's office by the respective state authorities and duplicate copies should be sent by manufacturers to the DCI while submitting them to the State Authority.

An acknowledged panel of experts with mandatory powers akin to those of a subcommittee and the DTAB should be accommodated into the Drug Control Authorities to *facilitate* summary *trails.*

Another such body under the Health Ministry consisting of academicians, health professionals etc. should be set up to do a time bound review of the drugs in the market therapeutic category wise, for an ongoing period of at least five years each.

7) Quality Control Labs

Information regarding *quality control* labs should be widely advertised so that consumer and health groups can directly get samples tested. The manufacturer should be made to pay the expenses for tests if the drugs prove substandard or spurious.

Provision of results within a specified time must be made mandatory, and the *batch numbers* of *substandard and spurious* drugs must be published. Batch numbers, names of drugs and manufacturers of potentially life threatening drugs should also be broadcast over AIR and Doordarshan and an effective withdrawal or recall system must be initiated.

8) Staffing

State Drug Control offices must be headed by efficient and well- trained pharmacists.

9) Drug Courts

Special *drug courts* are required to ensure summary trials to those violating the Drugs and Cosmetics Act, 1940.

10) Punishment

Since hardly any action is ever taken against violators of the Drugs and Cosmetics Act, publication of names of manufacturers, punishment awarded and reason for punishment must be made public to ensure at least social boycott of the culprits.

11) Purchase of Drugs

a) A high level committee must be formed to review the cases of spurious drugs and major problems associated with drug purchases for government health institutions. Periodic evaluation of drug purchase should be undertaken.

b) The lowest tender should not be the only criterion for drug purchases. Other pertinent criteria should be evolved and adhered to with priority to public sector companies.

c) Recommendations related to drug purchase by government institutions given by the *Lentin Commission* need to be followed.

12) Drugs to be purchased

The drugs purchased by the government institutions should be in keeping with the WHO Essential Drug List or a slightly longer rational drug list.

13) Drugs to be Avoided

At least those drugs banned by the DCI but which continue to be sold because of the stay orders obtained by the manufacturers, must *NOT* be purchased. Major fines must be imposed on those manufacturers who challenge the Drug Controller of India's ban on a drug. Routinely obtaining stay orders against drug bans has trivialized the authority of the Drug Control department. The Drugs and Cosmetics Act needs to be suitably reviewed and changes made to prevent this. Costly and irrational combination drugs should not be purchased when cheaper, equally effective or more effective single ingredient alternatives exist.

14) Drug Testing Labs (In House)

All major institutions must have their *own* drug testing labs with qualified and competent personnel.

15) Medical Audit

Medical Audit must be done periodically not just in Government institutions, but as part of drug utilisation studies, by the ICMR, the academic institutions etc. to keep track of the extent of the problem.

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